

## **REMARKS**

Reconsideration and withdrawal of the rejections of the claimed invention is respectfully requested in view of the amendments, remarks and enclosures herewith, which place the application in condition for allowance.

### **I. STATUS OF SPECIFICATION, CLAIMS AND FORMAL MATTERS**

Claims 1-20 are still pending in this application. Claim 1 has been amended to add the limitations of original claims 4, 10 and 11. No new matter has been added by this amendment. The applicants reserve the right to pursue the scope of the originally filed claims in a continuation application.

It is submitted that the claims, herewith and as originally presented, are patentably distinct over the prior art cited in the Office Action, and that these claims were in full compliance with the requirements of 35 U.S.C. § 112. The amendments of the claims, as presented herein, are not made for purposes of patentability within the meaning of 35 U.S.C. §§§§ 101, 102, 103 or 112. Rather, these amendments and additions are made simply for clarification and to round out the scope of protection to which Applicants are entitled.

### **II. THE OBVIOUSNESS-TYPE DOUBLE PATENTING REJECTION HAS BEEN OVERCOME**

Claims 1-20 have been provisionally rejected under obviousness-type double patenting over claims 1-28 of copending Application No. 10/835,997 in view of U.S. Patent 6,348,501 ("the '501 patent"). While there are certain similarities between the analysis for an obviousness rejection and an obviousness-type double patenting (ODP) rejection, the rejections are not the same, i.e. the analysis for an ODP rejection is limited to a comparison of the respective claims and does not allow for the use of secondary references except for explanatory purposes (e.g. defining the meaning of a claim term). *See MPEP 804.*

However, in the present case, the '501 patent is being used to address a missing element of the applicants' claim. Therefore, the use of the '501 patent is *prima facie* evidence that a basis for ODP does not exist and this rejection should be withdrawn.

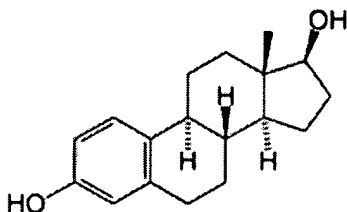
### **III. THE 35 U.S.C. 103(a) REJECTION HAS BEEN OVERCOME**

Claims 1-11, 13-15 and 17-20 were rejected as allegedly being obvious by Chien et al. (US 5,788,983 – "Chien") in view of Holt et al. (US 6,348,501 – "Holt"), Embil et al. (US

6,818,671 – “Embil”) and Schacht et al. (US 2005-0079206 – “Schacht”). The applicants request reconsideration of this rejection for the following reasons.

In order to establish a holding of *prima facie* obviousness, each of the applicants claim limitations must be taught or suggest by the prior art and if the combinations of limitations are found in more than one reference, there must be some reason either within the prior art or from the knowledge from those of ordinary skill in the art to combine the respective teachings. However, there are several differences between the applicants’ claims and the combination of Chien, Holt, Embil and Schacht.

As with the Oloff reference previously relied upon, Chien, while generally directed toward the delivery of an active agent is primarily directed toward the delivery of a *estrogenic steroid* (figure for estradiol shown below for representative example):



No mention of capsaicin is made anywhere in the Chien reference (difference 1).

The applicants agree with the assessment made in the Office Action that Chien also does not explicitly teach capsaicin as an active agent being dissolved in microreservoirs (difference 2) or that the polysiloxane matrix is a mixture of a polysiloxane of medium tack and a polysiloxane of high tack (difference 3).

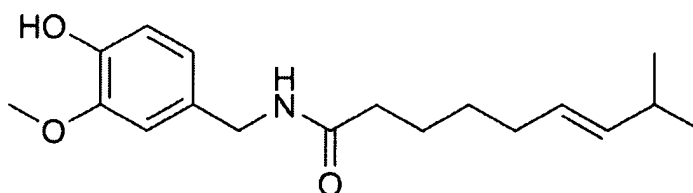
The applicants also note that Chien also fails to teach that the polysiloxane matrix is a self-adhesive amine-resistant polysiloxane matrix (difference 4) and that Chien requires a “means which desirably provide variable transdermal absorption rates”, i.e. a permeability-regulating polymer membrane (see Figure 1 and 2 of Chien and col. 3, lines 45-54) – (difference 5).

While there is no limit on the number of references which can be used to support an obviousness rejection, the greater the number of references needed is generally an indicia of non-obviousness especially if only selected elements are relied upon in the secondary reference, i.e. an obvious to try rationale is permissible, but only if there is a finite number of identified,

predictable solutions which have a reasonable expectation of success. The addition of Holt, Embil and Schacht creates virtually an infinite number of possible solutions when the entire reference of Chien, Holt, Embil and Schacht are considered as a whole. *See MPEP 2141.02.*

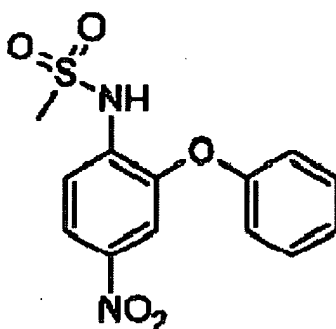
As previously noted, the Holt reference does not teach the missing elements of Chien and does not refer to an analogous invention to Chien which would suggest to one ordinary skill in the art that individual elements of Holt could be used with Oloff.

Holt does teach the use of capsaicin (see figure below):



However, Holt's invention is part of a *lotion* (a suspension or dispersion) where the capsaicin is *encapsulated* by an encapsulation agent. This is neither the mechanism of delivery of the active agent for either the applicants' invention or for Chien. While the applicant's invention (topical patch) and Chien's device for transdermal administration are directed toward controlled release of an active agent, Holt's lotion has no such control and as such one of ordinary skill in the art would not look to Holt's teachings as being relevant for the applicants' invention or that of Chien. Even if it were permissible to combine Holt with Chien, the combined teachings would still lack a teaching of the use of microreservoirs and that the active agents are dissolved therein and that the concentration of capsaicin or a capsaicin analog is at 20 and 90% by weight of the saturation concentration.

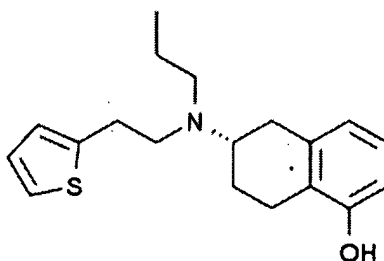
The description of the Embil reference in the Office Action is very misleading in that while capsaicin is mentioned in the specification, it is mentioned as an optional ingredient ("Other ingredients may also optionally be included in the composition, for example, capsicum oleoresin, capsaicin..." – see col. 3, lines 57-58). However, one of ordinary skill in the art would clearly see that the Embil's invention is not directed toward capsaicin as the primary active ingredient, but towards the delivery of *nimesulide* (see Abstract and Summary of the Invention), a COX-2 selective NSAID– see figure below:



The amphiphilic solvent systems mentioned in Embil (1,3 butylene glycol, dipropylene glycol and DGME) are for the purpose of enhancing the delivery nimesulide; one of ordinary skill in the art considering Embil as a whole would not recognize these systems as for enhancing the delivery of capsaicin especially when Embil does not teach or suggest that the amphiphilic solvent systems are to be incorporated into the microreservoirs of the applicants' claimed invention.

Moreover, as with the Holt reference, Embil is non-analogous to the applicants' invention or that of Chien in that Embil is directed toward the composition being in the form of a gel, solution, ointment or spray and not toward a topical patch which comprises a self-adhesive amine resistant polysiloxane matrix wherein the matrix contains liquid microreservoir droplets. The gel, solution, ointment or spray does not produce the controlled release of active agent as in Chien or the applicants' claimed invention.

The Schacht reference is clearly directed toward a means for improving transdermal delivery of *rotigotine*, a dopamine agonist compound used in the treatment of Parkinson's disease (see Abstract and Summary of the Invention) – see figure below.



Obviously, Schacht does not teach or suggest the use of capsaicin in their microreservoirs. However, Schacht also does not teach the use of amphiphilic solvents with capsaicin in the microreservoirs which is part of the applicants invention (and serves to keep the level of

capsaicin in the microreservoirs high as the amphiphilic solvent is delivered with the capsaicin transdermally).

In addition, neither Holt, Embil or Schacht address Chien's omission for the teaching the use of an amine resistant polysiloxane or for teaching the requisite concentration of capsaicin in the microreservoir droplets.

Lastly, as the determination of obviousness requires consideration of the references as a whole, it is unclear why one of ordinary skill in the art would selectively ignore all of the remaining elements from the Chien, Holt, Embil and Schacht references not cited in the Office Action especially when the skilled artisan, unlike the Examiner, would not have the applicants' claims as a blueprint to arrive at the applicants' claimed invention. The selective picking and choosing of elements from Chien, Holt, Embil and Schacht is particularly inappropriate as the respective references have little to no similarity in the chemical structures of their primary active ingredients.

For these reasons, the combination of Chien, Holt, Embil and Schacht does not support a holding of *prima facie* obviousness as there was not a finite number of identified and predictable solutions and/or because all of the claim limitations were not taught by the combination of references.

**Claim 12 was rejected** as allegedly being obvious over Chien, Holt, Embil and Schacht and further view of Brown et al. (US 7,247,315 – "Brown"). The applicants request reconsideration of this rejection for the following reasons.

The applicants' arguments with respect to the combination of Chien, Holt, Embil and Schacht is considered to be repeated here. Brown does not remedy the deficiencies of the combination of Chien, Holt, Embil and Schacht and is not even appropriate for its intended use to support the rejection of claim 12; Brown only serves to add to the number of possible number of solutions and further weakens any assertion of obviousness.

There is simply no reason why one of ordinary skill in the art (who does not possess a copy of the applicants' claims to act as a blueprint) would be specifically directed toward silicone oil in Brown to the exclusion of all other possible teachings within the Brown reference. This is especially true in this case as Brown is directed toward yet another means of delivery for yet another type active agent (*fentanyl* or *sufentanyl* in Brown) which is different from Chien,

Holt, Embil and Schacht's delivery methods, i.e. Brown is directed toward the delivery of the active ingredient from a solid drug reservoir which differs from the microdispersions of Oloff and encapsulating agents of Holt. There would be no expectation of success that taking an individual element from Brown would not change the function of either Chien, Holt, Embil and Schacht's invention alone or in combination.

**Claim 16 was rejected** as allegedly being obvious over Chien, Holt, Embil and Schacht in view of Peterson (US 5,494,680). The applicants request reconsideration of this rejection for the following reasons.

The applicants' arguments with respect to the combination of Chien, Holt, Embil and Schacht is considered to be repeated here. Peterson does not remedy the deficiencies of the combination of Chien, Holt, Embil and Schacht and similar to the objection of the use of Brown above, Peterson is being used for specific elements to the exclusion of considering the invention as a whole, i.e. Peterson also is directed to a different delivery system than Chien, Holt, Embil and Schacht and also a different active agent than Chien, Holt, Embil and Schacht and there is no reason to pick specific elements from Peterson to the exclusion of their other teachings.

**Claim 17 was rejected** as allegedly being obvious over Chien, Holt, Embil and Schacht in view of Robbins (US 6,239,180). The applicants request reconsideration of this rejection for the following reasons.

Robbins does refer to a method of treating neuropathic pain with capsaicin, but does not teach the topical patch of the applicants' invention for the reasons cited above with respect to Chien, Holt, Embil and Schacht.

**CONCLUSION**

In view of the remarks and amendments herewith, the application is believed to be in condition for allowance. Favorable reconsideration of the application and prompt issuance of a Notice of Allowance are earnestly solicited. The undersigned looks forward to hearing favorably from the Examiner at an early date, and, the Examiner is invited to telephonically contact the undersigned to advance prosecution. The Commission is authorized to charge any fee occasioned by this paper, or credit any overpayment of such fees, to Deposit Account No. 50-0320.

Respectfully submitted,  
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